

*Study: 99% of Medicine Cups and Dosage Devices Flawed*

*New bill will make FDA recommendations on medicine cups and dosage devices mandatory*

Huntington, NY— On Monday, Rep. Steve Israel (D-Huntington) will announce new legislation to make medicine cups and other dosage devices commonly used to give medicine to children safer. A recent study published in the December 2010 Journal of the American Medical Association found that 99 percent of medicine cups and dosage devices were flawed.

“When we give our kids medicine, we hope we’re making them better. But when nearly all the medicine cups and dosing devices used with our kids’ medicine are flawed, there is a chance we could be making them worse. Why would a medicine’s label say tablespoons when the dosing cup is in teaspoons? We’ve been too lax about these flaws for too long,” said Rep. Israel. “There is nothing more important to a parent than the health of our children. That’s why I’m introducing a bill to impose mandatory requirements to help make medicine cups and dosing devices safer and easier to use.”

According to the FDA’s Guidance for Industry on the issue, “OTC liquid drug products in the marketplace are packaged with dosage delivery devices that bear markings that are inconsistent with the labeled dosage directions... There have been numerous reports of accidental overdose that were attributed, in part, to markings on measured dosage cups for OTC liquid drug products that were misleading or incompatible with the labeled dosage directions for use.”

Rep. Israel is introducing new legislation called the Protecting Our Kids’ Medicine Act to impose mandatory requirements on medicine cups and dosage devices, making them easier to use and safer for our children and families. The bill is based on voluntary guidelines issued by the FDA in 2009.

The Protecting Our Kids’ Medicine Act, requires that:

- Dosage delivery devices must be included for all over the counter liquid drug products;
- The units of measure marked on the medicine cup or other dosing device must be the same as the units of measure in the labeled directions (i.e., don’t tell parents to give one teaspoon of liquid cold medicine to their kid on the box and then provide them with a measuring cup in milliliters);
- If units of measure are abbreviated on the dosage delivery device, then the abbreviation used on the device must be the same abbreviation used in the labeled directions (i.e., don’t tell parents to give one “mL” of liquid cold medicine to their kid on the box and then provide them with a measuring cup that uses the abbreviation “ml” or “mil”);
- Any decimals or fractions listed on the dosage delivery device must be listed as clearly as possible;
- Dosage delivery devices may not bear extraneous or unnecessary markings that may be confusing; and
- The markings on dosage delivery devices must be clearly visible and may not be obscured when the product is added to the device.

The medical community has known about the issue of flawed dosage devices for at least 35

years. A 1975 study in the medical journal Pediatrics found evidence of incorrect dosing in liquid medications, especially great variability when using regular household spoons instead of measuring cups. The FDA has issued previous guidance on the issue, but as demonstrated by the 2009 study, the problems with medicine cups and dosage devices have persisted.

More than half of U.S. children are exposed to 1 or more medications in a given week, and more than half of these are over-the-counter medications. Moreover, as many as 40 percent to 60 percent of parents make errors when administering medications to their children (Source: 2009 survey in Pediatrics, cited in the December 2010 Journal of the American Medical Association report).

An investigation by the Centers for Disease Control found that in 2004 and 2005 an estimated 1,159 children under the age of 2 years old were treated in U.S. emergency rooms because of adverse events associated with cough and cold medications, including three infant deaths whose underlying cause was cough and cold medications.

Rep. Israel will introduce his legislation in January when Congress returns for session.